

PATENT COOPERATION TREATY

PCT

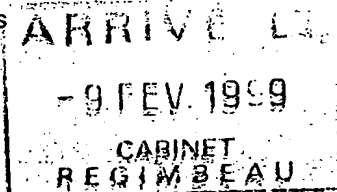
NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:

MARTIN, Jean-Jacques
Cabinet Regimbeau
26, avenue Kléber
F-75116 Paris
FRANCE



Date of mailing (day/month/year) 28 January 1999 (28.01.99)		
Applicant's or agent's file reference 339217/17609		IMPORTANT NOTICE
International application No. PCT/IB98/01091	International filing date (day/month/year) 16 July 1998 (16.07.98)	Priority date (day/month/year) 16 July 1997 (16.07.97)
Applicant INSTITUT PASTEUR et al		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
AU, BR, CA, CN, EP, IL, JP, KP, KR, US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AL, AM, AP, AT, AZ, BA, BB, BG, BY, CH, CU, CZ, DE, DK, EA, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IS, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, OA, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 28 January 1999 (28.01.99) under No. WO 99/04005

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer J. Zahra
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 09 March 1999 (09.03.99)	
International application No. PCT/IB98/01091	Applicant's or agent's file reference 339217/17609
International filing date (day/month/year) 16 July 1998 (16.07.98)	Priority date (day/month/year) 16 July 1997 (16.07.97)
Applicant GICQUEL, Brigitte et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:08 February 1999 (08.02.99)☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Lazar Joseph Panakal Telephone No.: (41-22) 338.83.38
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PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 339217/17609	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IB 98/01091	International filing date (day/month/year) 16/07/1998	(Earliest) Priority Date (day/month/year) 16/07/1997
Applicant INSTITUT PASTEUR et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).
2. ☐ Unity of invention is lacking (see Box II).
3. ☒ The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
 - ☐ filed with the international application.
 - ☒ furnished by the applicant separately from the international application,
 - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - ☐ Transcribed by this Authority
4. With regard to the title,
 - ☒ the text is approved as submitted by the applicant.
 - ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract**,
 - ☒ the text is approved as submitted by the applicant.
 - ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the **drawings** to be published with the abstract is:

Figure No. _____

 - ☐ as suggested by the applicant.
 - ☐ because the applicant failed to suggest a figure.
 - ☐ because this figure better characterizes the invention.

☒ None of the figures.



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : C12N 15/31, C07K 14/35, C12N 15/62, C07K 19/00, C12N 15/74, G01N 33/53, C12N 1/21, C07K 16/12, A61K 39/04, C12Q 1/68 // (C12N 1/21, C12R 1:32, 1:19, 1:34, 1:38, 1:42)	A1	(11) International Publication Number: WO 99/04005 (43) International Publication Date: 28 January 1999 (28.01.99)
(21) International Application Number: PCT/IB98/01091 (22) International Filing Date: 16 July 1998 (16.07.98) (30) Priority Data: 60/052,631 16 July 1997 (16.07.97) US (71) Applicants (for all designated States except US): INSTITUT PASTEUR [FR/FR]; 28, rue du Docteur Roux, F-75015 Paris (FR). STATENS SERUM INSTITUT [DK/DK]; Artillerivej 5, DK-2300 Copenhagen 5 (DK). (72) Inventors; and (75) Inventors/Applicants (for US only): GICQUEL, Brigitte [FR/FR]; 8, rue Daguerre, F-75014 Paris (FR). BERTHET, François-Xavier [FR/FR]; 86, rue Olivier de Serres, F-75015 Paris (FR). ANDERSEN, Peter [DK/DK]; Lystrupvej 7, DK-2700 Brønshøj (DK). RASMUSSEN, Peter, Birk [DK/DK]; Rudolph Bergsgade 5, DK-2100 København Ø (DK). (74) Agents: MARTIN, Jean-Jacques et al.; Cabinet Regimbeau, 26, avenue Kléber, F-75116 Paris (FR).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: A POLYNUCLEOTIDE FUNCTIONALLY CODING FOR THE LHP PROTEIN FROM MYCOBACTERIUM TUBERCULOSIS, ITS BIOLOGICALLY ACTIVE DERIVATIVE FRAGMENTS, AS WELL AS METHODS USING THE SAME		
(57) Abstract <p>The present invention is directed to a polynucleotide carrying a n open reading frame coding for an antigenic polypeptide from Mycobacterium tuberculosis, named lhp, which is placed under the control of its own regulation signals which are functional in mycobacteria, specially in mycobacteria belonging to the Mycobacterium tuberculosis complex and also in fast growing mycobacteria such as Mycobacterium smegmatis. The invention is also directed to the polypeptide LHP encoded by lhp and most preferably to suitable antigenic portions of LHP as well as to oligomeric polypeptides containing more than one unit of LHP or an antigenic portion of LHP. The invention concerns also immunogenic and vaccine compositions containing a polypeptide or an oligomeric polypeptide such as defined above, as well as antibodies directed specifically against such polypeptides that are useful as diagnostic reagents. In another embodiment, the present invention is directed to a polynucleotide carrying the natural regulation signals of lhp which is useful in order to express heterologous proteins in mycobacteria. Finally, the present invention is directed to oligonucleotides comprising at least 12 consecutive nucleotides from the regulation sequence of lhp which are useful as reagents for detecting the presence of Mycobacterium tuberculosis in a biological sample.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
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BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
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DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTER IONAL SEARCH REPORT

International Application No

PCT/IB 98/01091

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 C12N15/31 C07K14/35 C12N15/62 C07K19/00 C12N15/74
 G01N33/53 C12N1/21 C07K16/12 A61K39/04 C12Q1/68
 //(C12N1/21, C12R1:32, 1:19, 1:34, 1:38, 1:42)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 C12N C07K G01N A61K C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 97 09428 A (CORIXA CORP; REED; SKEIKY; DILLON; CAMPOS-NETO; HOUGHTON; VEDVICK (US)) 13 March 1997 cited in the application see abstract see page 17, line 4-22 see page 18, line 12-20 see page 23, line 7-24 see page 37, line 12 - page 42 Seq.ID:46, 47, 88, 93-98, 112-119 see page 83 - page 84 see page 124 see page 128 - page 131 see page 143 - page 150 see page 158 - page 163; claims --- -/-</p>	<p>1-7, 9-13, 15-53</p>

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

22 October 1998

Date of mailing of the international search report

28 10. 98

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Macchia, G

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/IB 98/01091

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 09429 A (CORIXA CORP; REED; SKEIKY; DILLON; CAMPOS-NETO; HOUGHTON; VEDVICK (US)) 13 March 1997 cited in the application	1-7, 9-13, 15-53
A	see abstract see page 14, line 23 - page 15, line 2 see page 35, line 21 - page 36, line 13 see page 39, line 22 - page 42 Seq.ID:46, 47, 89, 107-114 see page 88 - page 89 see page 135 - page 136 see page 157 - page 164 see page 173 - page 181; claims see figures 3-5	54,55
X	--- WO 96 25519 A (PATHOGENESIS CORPORATION (US); STOVER C.K. (US); MAHAIRAS G.G. (US)) 22 August 1996 see page 1, line 28 - page 4, line 31 see page 11, line 1-14; figures 1,4 see page 37, line 13 - page 38, line 8 see page 41 - page 44; claims	1-6, 9-12,15, 34-43
P,X	--- Database EMBL R55U027, Entry AF004671 Accession number AF004671 29 June 1998 99% identity with Seq.ID:1 XP002081660 see the whole document	1,2,4,5, 17,20
P,X	--- WO 98 16645 A (CORIXA CORP; REED; SKEIKY; DILLON; CAMPOS-NETO; HOUGHTON; VEDVICK (US)) 23 April 1998 see abstract see page 21, line 10 - page 28, line 17 Seq.ID:46, 47, 89, 107-114, 147, 148, 208, 209 see page 90 see page 141 - page 147 see page 162 - page 166 see page 218 - page 226 see page 227 - page 236; claims ---	1-6,9, 16,17, 20,22, 25,30-43
	-/--	

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/IB 98/01091

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	<p>WO 98 16646 A (CORIXA CORP; REED; SKEIKY; DILLON; CAMPOS-NETO; HOUGHTON; VEDVICK (US)) 23 April 1998</p> <p>see abstract see page 23, line 27 - page 29, line 7 see page 41, line 12 - page 49, line 3 Seq.ID:46, 47, 88, 93-98, 112-119, 152, 153, 213, 214 see page 88 - page 89 see page 117 - page 118 see page 121 - page 123 see page 135 - page 141 see page 154 - page 157 see page 204 - page 211 see page 212 - page 217; claims</p>	<p>1-6,9, 10,12, 16,17, 20-22, 24, 26-29, 31,33</p>
A	<p>EP 0 400 973 A (AJINOMOTO KK ;YAMADA TAKESHI (JP)) 5 December 1990 see column 5, line 37-41 see column 6, line 6-11</p>	<p>10-12,15</p>
A	<p>TAM J.P.: "Synthetic peptide vaccine design: synthesis and properties of a high-density multiple antigenic peptide system" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, vol. 85, August 1988, pages 5409-5413, XP002070407 cited in the application see the whole document</p>	<p>18,19,23</p>
A	<p>SATHISH M. ET AL.: "Identification and characterization of antigenic determinants of Mycobacterium leprae that react with antibodies in sera of leprosy patients" INFECTION AND IMMUNITY, vol. 58, no. 5, May 1990, pages 1327-1336, XP002081659 cited in the application</p>	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 98/01091

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9709428 A	13-03-1997	AU 7158696 A	27-03-1997
		EP 0851927 A	08-07-1998
		NO 980883 A	27-04-1998
		PL 325373 A	20-07-1998
WO 9709429 A	13-03-1997	AU 7158796 A	27-03-1997
		EP 0850305 A	01-07-1998
WO 9625519 A	22-08-1996	US 5700683 A	23-12-1997
		AU 4979696 A	04-09-1996
WO 9816645 A	23-04-1998	AU 4750597 A	11-05-1998
WO 9816646 A	23-04-1998	AU 4814497 A	11-05-1998
EP 0400973 A	05-12-1990	DE 69027956 D	05-09-1996
		DE 69027956 T	06-03-1997
		JP 3072888 A	28-03-1991

PATENT COOPERATION TREATY

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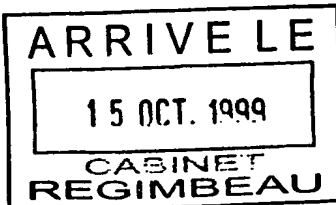
From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

To:

MARTIN, Jean-Jacques
Cabinet REGIMBEAU
26, avenue Kléber
75116 Paris
FRANCE



Date of mailing
(day/month/year)

08. 10. 99

Applicant's or agent's file reference
339217/17609

IMPORTANT NOTIFICATION

International application No.
PCT/IB98/01091

International filing date (day/month/year)
16/07/1998

Priority date (day/month/year)
16/07/1997

Applicant
INSTITUT PASTEUR et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



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D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer

Schou, S

Tel. +49 89 2399-8062



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 339217/17609	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB98/01091	International filing date (day/month/year) 16/07/1998	Priority date (day/month/year) 16/07/1997
International Patent Classification (IPC) or national classification and IPC C12N15/31		
Applicant INSTITUT PASTEUR et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 08/02/1999	Date of completion of this report 08.10.99
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Grosskopf, R  Telephone No. +49 89 2399 8714

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB98/01091

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-59 as originally filed

Claims, No.:

1-55 as originally filed

Drawings, sheets:

1/13-13/13 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 1-55.

because:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB98/01091

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-55 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. .

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB98/01091

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1
Inventive step (IS)	Yes: Claims	
	No: Claims	1-55
Industrial applicability (IA)	Yes: Claims	1-55
	No: Claims	

2. Citations and explanations

see separate sheet

Ad item V:

The basis for all claimed subject-matter appears to be the sequence of Claim 1(a). Said sequence, however, is (with three or four exceptions) identical to a sequence disclosed in D1 (WO 97/09248; see e.g. SEQ ID NO: 112). Since the sequence (or subsequences thereof or the corresponding polypeptides) of D1 has been used for the same purposes, at present, not **any** subject-matter is recognisable which might constitute the basis for an inventive claim.

Ad item III and IV:

Moreover, the present set of claims is objectionable for so many other reasons that it is impossible to carry out a meaningful or even complete examination with regard to each and every embodiment claimed.

Thus, this opinion has to be limited to some of the (basic) objections.

A detailed final examination of any subject-matter (i.e. in the final opinion) could only be carried out if at least these basic objections were removed.

First, the set of claims comprises a myriad of different entities, said entities not being linked by a common structural feature and thus not being linked by a common inventive concept (as one example see e.g. items (e) and (g) of Claim 1). In order to comply with the requirements for a unitary concept, only the claiming of those entities were acceptable which share such a common structural **special** feature, i.e. a feature which is common to all entities claimed **and** which is suitable to distinguish the claimed entities from the prior art (e.g. D1).

It goes without saying that in view of the identity of the sequences disclosed in D1 and the present application, such a feature is not even recognisable for **two** different entities (let alone for more).

As a consequence, at best **one** independently claimed entity could be accepted (but not different alternatives within one claim).

Any broadening (see e.g. Claim 1 (e) to (g)) must not only result in an objection for lack of clarity (since the scope of said subparts are totally unlimited) but, especially in view of the prior art, in further novelty objections.